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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|-------------------|
| 09/725,178 | 11/29/2000 | Bettina Mockel | P 273989 990168 BT | 8596 |
| 909 | 7590 | 10/20/2004 | EXAMINER | |
| PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102 | | | | HUTSON, RICHARD G |
| | | ART UNIT | | PAPER NUMBER |
| | | 1652 | | |

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/725,178 | MOCKEL ET AL. | |
| | Examiner Richard G. Hutson | Art Unit 1652 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 July 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,5-7 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 1,5,7,27-29 and 31-33 is/are allowed.
- 6) Claim(s) 2 is/are rejected.
- 7) Claim(s) 6,22,23 and 30 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment of claim 6 cancellation of claim 4 and the addition of new claims 27-33 in the paper of 7/29/2004 is acknowledged. Claims 1, 2, 5-7 and 21-33 are at issue and are present for examination.

Applicants' arguments filed on 7/29/2004, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claims 6, 22, 23 and 30 are objected to because of the following informalities:

Newly amended claim 6 (claims 22 and 23 dependent on) recites "...wherein said nucleotide sequence **or** fragment thereof encode for a polypeptide having phosphoglycerate mutase activity". This should be amended to "...wherein said nucleotide sequence **and the** fragment thereof encode for a polypeptide having phosphoglycerate mutase activity".

Claim 30 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent which refers to more than one other claim shall refer to such other claims in the alternative only . See MPEP § 608.01(n).

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office actions as applied to previous claim 2. In response to this rejection, applicants traverse on the following basis.

Applicants point out that claim 2 is directed to the isolated polynucleotide according to claim 1 wherein said polynucleotide is isolated from a coryneform bacterium and that claim 1 is directed to an isolated polynucleotide comprising a polynucleotide sequence selected from the group consisting of a polynucleotide encoding a polypeptide containing an amino acid sequence which is at least 90% identical to the amino acid sequence of SEQ ID NO: 2, the polypeptide having phosphoglycerate activity. Applicants submit that these structural and functional characteristics of the subject matter meet the written description Guidelines of the United States Patent and Trademark Office. Applicants emphasize in particular Example 14 of the guidelines in asserting that like this example, applicants claims are drawn to variant polynucleotides which encode polypeptides having 90 or 95% variation

Art Unit: 1652

while maintaining phosphoglycerate mutase activity. Applicants further assaying for phosphoglycerate mutase activity was a "well-established procedure" in the art at the time of filing. Furthermore applicants submit that they have discovered overexpression of the gpm gene increases the production of L-lysine. Thus applicants conclude that based on the above, the structural and functional limitations of claim 2 (via claim 1) are described in the specification in such a way as to convey to one of skilled in the art that applicants had possession of a finite number of claimed polynucleotides.

Applicants traversal is not found persuasive, because as previously stated,

In the instant specification, a single polynucleotide encoding SEQ ID NO: 2 is fully described in the form of SEQ ID NO:1, wherein SEQ ID NO: 2 has phosphoglycerate mutase activity. This description also adequately describes a genus, within the sequence identity limitations of the instant claims, of polynucleotides encoding proteins having this particular function. Those sequences that are "naturally occurring" or isolated from coryneform bacteria are a subset of this genus. The specification does not adequately describe this subset according to its structure so that one of skill in the art would be able to predict naturally occurring sequences, particularly in view of the larger genus that includes both naturally and "manufactured" sequences. Therefore, the instant claims are not adequately described.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Art Unit: 1652

The rejection of claims 1, 2 4 and 21-23 under 35 U.S.C. 112, first paragraph, enablement is hereby withdrawn based on applicants amendment and cancellation of the claims and applicants traversal in the paper of 7/29/2004.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1652

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G. Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
10/6/2004